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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/715,730	11/18/2003	George F. Fattman	CV0326 NP	4899
26079	7590	04/17/2006	EXAMINER	
BRISTOL-MYERS SQUIBB COMPANY 100 HEADQUARTERS PARK DRIVE SKILLMAN, NJ 08558			HILL, LAURA C	
			ART UNIT	PAPER NUMBER
			3761	

DATE MAILED: 04/17/2006

Please find below and/or attached an Office communication concerning this application or proceeding.



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APPLICATION NO./ CONTROL NO.	FILING DATE	FIRST NAMED INVENTOR / PATENT IN REEXAMINATION	ATTORNEY DOCKET NO.
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EXAMINER

ART UNIT PAPER

20060410

DATE MAILED:

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner for Patents

Office Action Summary	Application No.	Applicant(s)
	10/715,730 Examiner Laura C. Hill	FATTMAN, GEORGE F. Art Unit 3761

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) Responsive to communication(s) filed on 16 February 2006.
 2a) This action is FINAL. 2b) This action is non-final.
 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) Claim(s) 1-3,5-18 and 21 is/are pending in the application.
 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
 5) Claim(s) _____ is/are allowed.
 6) Claim(s) 1-3,5-18 and 21 is/are rejected.
 7) Claim(s) _____ is/are objected to.
 8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) The specification is objected to by the Examiner.
 10) The drawing(s) filed on _____ is/are: a) accepted or b) objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 a) All b) Some * c) None of:
 1. Certified copies of the priority documents have been received.
 2. Certified copies of the priority documents have been received in Application No. _____.
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Response to Arguments

1. Applicant's arguments filed 16 February 2006 with respect to claims 1-3, 5-18 and 21 have been considered but are moot in view of the new ground(s) of rejection as discussed below.

Specification

2. It is noted that the title has been changed to 'Ostomy Pouch Adhesives Such As Polysiloxanes That Are Resistant to Stomal Effluent.'

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

3. Claims 1-2, 5-7 and 21 are rejected under 35 U.S.C. 102(b) as being anticipated by Wagner (US 6,520,943; herein 'Wagner'). Wagner discloses a two component ostomy faceplate and coupling system (column 3, lines 30-31) comprising a body attaching blotter ring/adhesive coated interface 25 that adheres to the circumference of the wearer's stoma 5 (column 4, lines 50-53 and column 5, lines 9-13) and a pouch component (figure 1), said adhesive component 25 being replaceable/removable (column 4, line 67-column 5, line 3) and positioned around the stoma to collect stoma fluid (figures 3-4), said adhesive interface 25 including polydimethylsiloxane (column 7,

line 62-column 8, line 7) for body conformation (column 5, lines 13-21) and resistance to stomal fluid migration (column 8, lines 30-35).

Claim Rejections - 35 USC § 103

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

4. Claims 1, 3, 5-13, 15-18, and 21 are rejected under 35 U.S.C. 103(a) as being unpatentable over McInally (US 4,831,070; herein 'McInally'). Regarding claims 1, 5, and 21 McInally discloses a pressure sensitive adhesive polydiorganosiloxane to form a seal between the stoma of an ostomy patient and an attached appliance (column 2, lines 60-66 and column 8, lines 34-48). McInally does not expressly disclose the ostomy device includes a pouch separable from the body wafer. Ostomy pouches including separable pouch and body wafer components are well known to those of ordinary skill in the art as supported by US 2,662,525 (figures 1 and 3); US 2,341,984 (figures 1-2); US 3,385,298 (figure 1); US 4,411,659 (figure 1); US 4,445,898 (figure 1); US 4,890,608 (figure 1); US 5,125,917 (figure 1). Therefore, one would have been motivated to modify the ostomy device of McInally with the separable pouch and body wafer components since all the references teach ostomy devices with separable components that are attached to one another. It would be obvious to one of ordinary skill in the art at the time the invention was made to modify the ostomy device, thus providing a two-piece separable ostomy device having a polysiloxane adhesive.

Regarding claim 3 McInally further discloses employing hydrocolloids in an amount up to about 30% of the elastomeric pressure sensitive adhesive (column 6, lines 42-48).

Regarding claims 5-7 McInally further discloses the composition may further include a trimethyl-endblocked polydimethylsiloxane fluid (column 6, lines 3-6) blended with silicate resin (column 3, lines 7-14).

Regarding claims 8-10 McInally further discloses blending of polysiloxanes (column 6, lines 57-66), wherein the silicate resin comprises silicon-bonded hydroxyl units (column 3, lines 53-57) and thus exhibiting silanol functionality.

Regarding claims 11 and 15-18 McInally does not expressly disclose the ratio of resin to pressure-sensitive adhesive, a plasticizing component percentage, peel strength, or coat weight in the ranges claimed. The ratio of resin to pressure-sensitive adhesive is a result-effective variable since the value depends on the amount of resin and adhesive, respectively, are utilized in the device. The plasticizing component of dry adhesive formulation percentage is a result effective variable since it depends on the solvent used. The peel strength is a result effective variable since the value depends on the resin to polymer ratio and the thickness of the adhesive as stated on page 16 of the instant specification. The coat weight is a result effective variable since it depends on the thickness of the adhesive and thus the amount of adhesive used on a given substrate. It would be obvious to one of ordinary skill in the art at the time the invention was made to modify McInally with the ratio, peel strength, plasticizing component, and coat weight values claimed, since it has been held that discovering an optimum value of

a result effective variable involves only routine skill in the art. *In re Boesch and Slaney*, 617 F. 2d 272, 205 USPQ 215 (CCPA 1980).

Regarding claims 12-13 McInally further discloses the use of additional property modifiers such as orthosilicates, plasticizers, co-solvents and other silicone or organic pressure sensitive adhesive materials (column 5, lines 23-36, column 6, lines 21-25).

5. Claim 14 is rejected under 35 U.S.C. 103(a) as being unpatentable over Wagner (US 6,520,943; herein 'Wagner') in view of Abber (WO 86/00532 A1; herein 'Abber').

Wagner does not expressly disclose a medicament for skin treatment or protection.

Abber discloses pressure sensitive adhesives such as dimethyl diphenyl siloxane gum with dimethyl siloxane gum/plasticizing oil and an organopolysiloxane resin for use on human skin for therapeutic devices (page 1, lines 13-16, page 5, lines 7-11). Abber further discloses the adhesive on the transdermal device permits medication to pass from the device, through the adhesive and into the skin (page 8, lines 23-27). One would be motivated to modify the adhesive-attaching ostomy device of Wagner with the medicament-permitting adhesive of Abber since both references disclose polysiloxane-type adhesives suitable for attaching devices to the skin. Therefore, it would be obvious to one of ordinary skill in the art at the time the invention was made to modify the adhesive-attaching ostomy device of McInally et al., thus providing an ostomy device containing a medicament.

Conclusion

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. McDougall et al. (WO 98/55157A2; herein 'McDougall') is cited

for showing a skin compatible adhesive for use on skin related medical appliances such as ostomy drainage pouches comprising a hydrocolloidal powder, antimicrobial agent and a polysiloxane.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Laura C. Hill whose telephone number is 571-272-7137. The examiner can normally be reached on Monday through Friday (off every other Friday).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Tatyana Zalukaeva can be reached on 571-272-1115. The fax phone

number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Laura C. Hill
Examiner
Art Unit 3761

LCH

LCH

TATYANA ZALUKAEVA
SUPERVISORY PRIMARY EXAMINER

Tatya